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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,109	06/21/2001	Anita Diu-Hercend	146 1353	3121
20311	7590	06/03/2004	EXAMINER	
MUSERLIAN AND LUCAS AND MERCANTI, LLP 475 PARK AVENUE SOUTH NEW YORK, NY 10016			LEFFERS JR, GERALD G	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 06/03/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/674,109

Applicant(s)

DIU-HERCEND ET AL.

Examiner

Gerald G Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-28 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13, 15, 16 and 18-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Receipt of a Request for Continued Examination (RCE), filed 1/27/2004, is acknowledged. Applicants were notified in a paper mailed 2/5/2004 that the request was improper due to the fact that prosecution in the case was not closed at that point and that the time period set forth in the previous action, mailed 11/19/2003, would continue to run. Subsequently, applicants filed a request for a Continued Prosecution Application under 37 CFR 1.53(d) on 2/25/2004, along with arguments concerning the restriction requirement as well as a Petition under Rule 181 to review the restriction requirement made by the examiner in the paper mailed 4/28/2003. Applicants were notified in a paper mailed 3/24/2004 that the Petition was denied and that the grounds for restriction provided by the examiner were proper.

The request for a continued prosecution application (CPA) under 37 CFR 1.53(d) filed on 2/25/2004 is acknowledged. 37 CFR 1.53(d)(1) was amended to provide that the CPA must be for a design patent and the prior application of the CPA must be a design application that is complete as defined by 37 CFR 1.51(b). See *Elimination of Continued Prosecution Application Practice as to Utility and Plant Patent Applications*, final rule, 68 *Fed. Reg.* 32376 (May 30, 2003), 1271 *Off. Gaz. Pat. Office* 143 (June 24, 2003). Since a CPA of this application is not permitted under 37 CFR 1.53(d)(1), the improper request for a CPA is being treated as a request for continued examination of this application under 37 CFR 1.114. Again, this request for an RCE is improper as prosecution in this application was not closed at the time of its submission. Moreover, the response/arguments and petition submitted on 2/25/2004 are considered as a response to the previous office action on the merits mailed 11/19/2003.

***Response to Arguments Filed 2/25/2004***

Essentially the same arguments were presented in the response filed 1/27/2004.

Applicants' response to the previous office action essentially argues that the restriction requirement made by the examiner was improper and that applicant inadvertently elected the wrong species. According to the response, the elected gene should have been YIL019w rather than YDR181c. There was no other argument or amendment to the claims presented in response to the grounds of rejection made in the office action mailed 11/19/2003 in the papers filed by applicants on 1/27/2004 and 2/25/2004.

As indicated above, and in the Petition Decision mailed 3/24/2004, the grounds provided by the examiner for restricting between the 360 different groups were proper. Moreover, there was *never* a species election requirement made by the examiner, as applicants' response continues to imply. Applicants elected a single invention, embodiments directed to the essential gene YDR181c, in their papers filed 8/26/2003 and have received an action on the merits for the elected embodiment. Arguments concerning an inadvertent error on applicants' part regarding the elected embodiments are thus moot at this stage of prosecution since there has already been an action on the merits. If applicants wish the embodiments directed to YIL019w to be examined, it will be necessary to file a new application directed to those specific embodiments.

Claims 13-28 are pending in the instant application. All of the remaining groups directed to other claims and/or different products (i.e. genes or gene products other than the YDR181c gene product) and/or different methods (i.e. *in vivo* methods) have been withdrawn as being nonelected inventions.

This action is FINAL.

### *Specification*

It is not clear that applicants have provided a sequence corresponding to YDR181c or its gene product (e.g. its not clear that the sequences are present in the sequence listing comprising 180 different sequences). These sequences are essential information required for practicing the claimed invention. If applicant has attempted to merely incorporate these sequences by reference, it is improper. The incorporation of essential material in the specification by reference to a foreign application or foreign patent, or to a publication is improper. If this is the case, Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). If the essential subject matter is in fact in the specification, applicant need only indicate the appropriate sequence identifier (i.e. SEQ ID NO). **This objection to the specification is maintained for reasons of record in the office action mailed 11/19/2003.**

### *Claim Objections*

Claims 13, 15-16, 18-28 are objected to because of the following informalities: each of the claims remains directed to nonelected embodiments. Applicants have elected methods directed to screening for antimycotics using the YDR181c gene product *in vitro*. Appropriate

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correction is required. **This objection to the claims is maintained for reasons of record in the office action mailed 11/19/2003.**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 15-16, 18-28 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **These grounds of rejection are maintained for reasons of record in the office action mailed 11/19/2003 and repeated below.**

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

*Nature of the invention:* The invention is complex, involving the use of a specific gene product encoded by YDR181c in *in vitro* assays to identify compounds that are antimycotic. The success of such methods depends on the role the YDR181c protein plays in the cell.

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*Breadth of the claims:* The claims encompass any assays that can be done *in vitro* using the YDR181c protein so long as the compounds identified can act as an “antimycotic compound”. A reasonable interpretation of the term is that the compound is fungicidal, or at least inhibitory of cell growth under some condition.

*Guidance of the specification/The existence of working examples:* The specification has only prophetic teachings as to the possible role in the yeast life cycle and a perfunctory statement that the gene products of the invention are “essential” to the cell (page 25, lines 27-36). No specific data for the YDR181c gene product is given.

*State of the art/Predictability of the art:* Post-filing art indicates that the role of the YDR181c gene product in the yeast cell cycle was poorly understood at the time of filing. Xu et al (Xu et al. Genetics, September 1999, Vol. 153, pages 13-23.) teach that YDR181c corresponds to a gene termed SAS4 that is involved in suppressing mating phenotypes in *S. cerevisiae* (e.g. Abstract, page 17, columns 1-2). In particular, the specification teaches that null mutations in SAS4 do not result in any detectable change in cell growth.

*The amount of experimentation necessary:* Given the combination of factors outlined above, it would take undue, unpredictable experimentation to construct and use the claimed methods to identify compounds that are antimycotic. This is particularly true in light of a lack of a defined role for the YDR181c gene product at the time of filing, and the subsequent finding that null mutants in the YDR181c gene are viable. For all of these reasons, the instant specification is not found to be enabling for the claimed methods of identifying an antimycotic compound.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 13, 15-16, 18-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **These grounds of rejection are maintained for reasons of record in the office action mailed 11/19/2003 and repeated below.**

Claims 13, 15-16, 18-28 are vague and indefinite in that the metes and bounds of the term “antimycotic” are unclear, particularly in the absence of an explicit definition in the specification or claims. Must the tested compound be lethal in order to be “antimycotic”? If the compound need only be inhibitory, then how inhibitory and in what manner must it be in order to satisfy the claim limitation?

Claims 13, 20-21 are vague and indefinite in that the metes and bounds of the term “functionally similar mycete gene” are unclear. How similar does the gene or gene product have to be in order to satisfy the claim limitation? Is similarity determined by some function, or sequence identity, or both? Claims 22-24 at least specify that the functionally similar protein is identified by its capability to complement the reference gene product *in vivo*.

Claims 27-28 are vague and indefinite in that there is no clear and positive prior antecedent basis for the phrase “the essential genes of *S. cerevisiae*” in claim 13, upon which each of these claims is dependent.

Claims 13, 16, 18-21, 25, 27 provide for the use of the YDR181c gene product, but, since the claim does not set forth any steps involved in the method/process, it is unclear what

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method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 13, 16, 18-21, 25, 27 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636

ggl

  
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